ORIGINAL

8EHQ-0796-13683S

REPORT NO. 94-1399-70

REPEATED INSULT PATCH TEST WITH IN FINISHED OIL (C 1234-24-2)

FOR

COMPANY SANITIZED

8EHQ-96-13683
88960000163S

HILL TOP RESEARCH, INC.
P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/831-1217
The Hill Top Companies
Hill Top Research, Inc. • Hill Top Pharmatest, Inc. • Hill Top Biolabs, Inc.

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APPENDICES

REPEATED INSULT PATCH TEST WITH

For:

SUMMARY

A Repeated Insult Patch Test was conducted in Miamiville and Norwood, Ohio by Hill Top Research, Inc., for . It investigated the skin sensitization potential of Test Article in finished oil (C 1234-24-2) and Test Article in finished oil (C 1234-24-2), a 50% dilution in mineral oil. Test Article A, (Mineral Oil U.S.P.) was also tested. All exposures were by 24 ± 1 hour contact under semi occluded patches. Patches were applied to sites on the upper arm. Any incidence of skin irritation observed to the test articles was also reported. The prefix code for these test articles was 94-1399-70.

HTR CODE	SPONSOR CODE
A	Mineral Oil U.S.P.
B	
C	.) in finished oil, 50%

Thirty subjects were enrolled in a pilot study to determine the appropriate dose to be used in the definitive study. Of these thirty subjects, fifteen received mineral oil and in finished oil (C 1234-24-2) and fifteen received mineral oil and finished oil (C 1234-24-2) (50%). Two subjects withdrew from the study for reasons unrelated to the test articles. Twenty-eight subjects completed the pilot study.

During the pilot study, one subject exhibited mild erythema at the eighth induction application to the mineral oil. This response was resolved by the ninth application. No other responses were observed during induction to the test articles. During challenge no reactions were observed for the test articles. Based on this observation, d oil (C 1234-24-2) was applied neat in the definitive study (designated as T).

SUMMARY (Continued)

One hundred-six subjects entered the definitive study. Seventeen subjects withdrew for reasons unrelated to the study. Eighty-nine subjects completed the definitive study.

In addition to in finished oil (C 1234-20-70), mineral oil was tested as a control for the definitive study. During the definitive study, one subject exhibited mild erythema to in finished oil (C 1234-24-2) at the second induction visit. This response was resolved by the fourth induction visit. A second subject exhibited mild erythema at the eighth induction visit. This response was resolved by the ninth induction visit. No other responses were observed during induction.

After the two-week rest period, 89 subjects reported to the test site on October 17, 1994, to receive their challenge application. Before application it was observed that Subject No. 31 exhibited mild erythema with a papular response covering the entire front area of the right arm (original patch site included). The subject stated that she had been working in her garden pulling weeds on Saturday, October 15, 1994 and that the response began on Sunday, October 16, 1994. Based on this observation, only the naive site (left arm) was patched for challenge. The subject exhibited no reaction at the 48-hour evaluation. At the 96-hour evaluation she exhibited mild erythema with papules, edema, and spreading to in finished oil (C 1234-24-2). The site patched with mineral oil (the control) was clea... ...8 and 96-hour evaluation.

On December 12, 1994, after a seven week rest period, Subject No. 31 received a confirmatory re-challenge with .n finished oil (C 1234-24-2) on the original (right arm) and naive (lower back) sites. The subject exhibited no response at the 48-hour evaluation. At the 96-hour evaluation the subject exhibited mild erythema with papules on the original and naive sites. The subject telephoned the Laboratory on December 19, 1994 and stated the reaction on her back had spread. The subject was evaluated that afternoon. On the original site (right arm) the response pattern remained the same as seen at the 96 hour evaluation. On the naive site (lower back) the response pattern of mild erythema with papules had begun to spread. Subject was clear on January 6, 1995.

Under the conditions of the study, the reactions exhibited by Subject No. 31 are indicative of clinical sensitization.

TITLE

Repeated Insult Patch Test with in finished oil (C 1234-24-2)
(Modified Draize Procedure)

OBJECTIVE

To evaluate n finished oil (C 1234-24-2) for the induction of contact sensitization by repetitive application to the skin of human subjects and to report any irritation observed with the test articles.

SPONSOR AND MONITOR

INVESTIGATIVE ORGANIZATION, TEST LOCATION AND PERSONNEL

Organization:	Hill Top Research, Inc.
Location:	Miamiville, Ohio 45147
Investigator:	Robert A. Harper, Ph.D.
Test Operation Supervisor:	Martha E. Plaza, M.B.A.
Senior Project Leader:	Bonnie Rue

CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, was reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board was obtained on July 12, 1994, prior to the initiation of the investigation (see Appendix IV).

GOOD CLINICAL PRACTICE STATEMENT

This study was conducted in accordance with Good Clinical Practices as outlined in Title 21 of the Code of Federal Regulation parts 50 and 56.

PROTOCOL

The study protocol, furnished by the Investigator and approved by the Study Sponsor, was followed (see Appendix V).

AMENDMENT TO PROTOCOL

There were three amendments to the protocol (shown in Appendix V).

DEVIATIONS FROM PROTOCOL

See Appendix II.

In the opinion of the Investigator, these deviations did not affect the outcome or integrity of the study.

TEST SUBJECTS

Prior to entrance into the study, written informed consent was obtained from each subject using the form shown in the protocol (see Appendix V).

Urine pregnancy tests were given to all females of child bearing potential at study start, week four and the beginning of Challenge (Week 6).

One hundred thirty six subjects who met the inclusion criteria started the study. One hundred sixteen subjects completed the study in both the pilot and definitive study.

Those subjects who did not complete the study and the reasons why are shown in Appendix III.

STUDY SCHEDULE

PILOT STUDY

Subject Nos.:	1 through 30
Study Initiated:	July 18, 1994
Study Completed:	August 26, 1994

STUDY SCHEDULE (Continued)

DEFINITIVE STUDY

Subject Nos.	Study Initiated	Study Completed
31 through 114	September 12, 1994	October 21, 1994
115 through 129	September 14, 1994	October 21, 1994
130 through 136	September 16, 1994	October 21, 1994
Rechallenge		
Subject No. 31	December 12, 1994	December 16, 1994

TEST ARTICLES/APPLICATION

The Test Sponsor furnished 885.2gm of n finished oil (C 1234-24-2) for the study on July 1, 1994.

The Investigator organization made a 50% dilution of n finished oil (C 1234-24-2) with mineral oil (Test Article C).

Test Articles B and C were dispensed at 0.1ml using an Eppendorf® semi-automatic pipette to the Webril® portion of the Professional Medical Products semi-occluded patch.

The Investigator organization provided Test Article A, Mineral Oil U.S.P., which was dispensed at 0.1 ml using an Eppendorf® semi-automatic pipette.

Test Article C was evaluated during the pilot study only. Test Article A (mineral oil) and Test Article B nished oil (C 1234-24-2) were evaluated on both the pilot and definitive studies.

ADVERSE EVENTS REPORT

There were no adverse events in this study.

RESULTS

Transcribed data for each individual subject are presented in Tables 1A through 1C. Summary totals for the complete panel of subjects observed during Induction and Challenge are located in these tables (see Appendix I).

During induction in the pilot study, Subject No. 22 exhibited mild erythema to mineral oil at the eighth induction evaluation and the response was clear by the ninth induction visit. No other responses were observed during the pilot study.

During the definitive study only the neat in finished oil (C 1234-24-2) was tested along with mineral oil. Subject No. 78 exhibited mild erythema to in finished oil (C 1234-24-2) at the eighth induction evaluation and the response was clear by the ninth induction visit. Subject No. 79 exhibited mild erythema to in finished oil (C 1234-24-2) at the second induction evaluation and the response was resolved by the fourth induction visit. These were the only responses seen during the induction phase.

After the two-week rest period, 89 subjects reported to the test site on October 17, 1994, to receive their challenge application. It was observed for Subject No. 31 that mild erythema with a papular response was covering the entire front area of the right arm, including the original patch site. Upon questioning, the subject stated that she had been working in the garden pulling weeds on Saturday, October 15, 1994. The following day, (Sunday, October 16, 1994) the response was noted by the subject. Based on this observation, only the adjacent site (left arm) was patched for challenge. No responses were observed to in finished oil (C 1234-24-2) at the 48-hour evaluation. By the 96-hour evaluation, mild erythema with papules and edema with spreading were observed. No responses were observed at the site patched with mineral oil throughout the challenge for this subject.

On December 19, 1994 after a seven week rest period, Subject No. 31 received a Confirmatory Rechallenge. in finished oil (C 1234-24-2) was patched on the original site (right arm) and a naive site (lower right back). The subject exhibited no response at the 48-hour evaluation. At the 96-hour evaluation the subject exhibited mild erythema with papules on both the original and the naive sites. The subject called on December 19, 1994 stating the reaction on her back was spreading with itching. The subject was evaluated that afternoon. On the original site (right arm), the response pattern remained the same as seen at the 96-hour evaluation. On the naive site (lower back) the response pattern exhibited mild erythema with definite spreading and itching.

RESULTS **(Continued)**

The reactions were clear by January 6, 1995.

CONCLUSIONS

Under the conditions of the study, the reactions exhibited by Subject No. 31 in finished oil (C 1234-24-2) are indicative of clinical sensitization.

Submitted for: ***HILL TOP RESEARCH, INC.***

By: Bonnie Rue 2-28-95
Bonnie Rue Date
Senior Project Leader

Martha E. Plaza 2/28/95
Martha E. Plaza, M.B.A Date
Test Operations Supervisor

Approved by: Robert A. Harper 3/1/95
Robert A. Harper, Ph.D. Date
Investigator

3-1-95
Jim Kreuzmann Date
General Manager

Quality Assurance Statement

This study was inspected in accordance with the Standard Operating Procedures of the Hill Top Companies. To assure compliance with the study protocol, the Quality Assurance Unit performed an inspection during the conduct of the study and completed an audit of the study records and the final report.

QA findings derived form the inspections during the conduct of the study and from the inspection of the final report are documented and have been reported to the appropriate personnel.

Date of Inspection	Auditor	Critical Phase Inspected
7-20-94	Elizabeth Camacho	Scoring

Report	Date Reviewed
Draft	11-16-94
Final	3-2-95

Reviewe by:

Auditor, Quality Assurance

3/2/95
Date

Ref.: 94-1399-70

APPENDIX I

(Total number of pages = 16)

Data Tables

(Pilot and Definitive)

Table 1A. Individual reaction scores following the application of test material.
Sample: A (MINERAL OIL)

Subject	Application Number 1	2		3			4			5			6			7			8			9			MU			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
1	0	0		0			0			0			0			0			0			0						0	0	0	0
2	0	0		0			0			0			0			0			0			0						0	0	0	0
3	0	0		0			0			0			0			0			0			0						0	0	0	0
4	0	0		0			0			0			0			0			0			0						0	0	0	0
5	0	0		0			0			0			0			0			0			0						0	0	0	0
6	0	0		0			0			0			0			0			0			0						0	0	0	0
7	0	0		0			0			0			0			0			0			0						0	0	0	0
8	0	0		0			0			0			0			0			0			0						0	0	0	0
9	LO	0		0			0			0			0			0			0			0						0	0	0	0
10	0	0		0			0			0			0			0			0			0						0	0	0	0
11	0	0		0			0			0			0			0			0			0						0	0	0	0
12	0	0		0			0			0			0			0			0			0						0	0	0	0
13	0	0		0			0			0			0			0			0			0						0	0	0	0
14	0	0		0			0			0			0			0			0			0						0	0	0	0
15	0	0		0			0			0			0			0			0			0						0	0	0	0
16	0	0		0			0			0			0			0			0			0						0	0	0	0
17	0	0		0			0			0			0			0			0			0						0	0	0	0
18	0	0		0			0			0			0			0			0			*0			0			0	0	0	0
19	0	0		0			0			0			0			0			-			0						0	0	0	0
20	LO	0		0			0			0			0			0			0			0						0	0	0	0
21	0	0		0			0			0			0			0			0			N9G						Dropped			
22	0	0		0			0			0			0			0			1			0						0	0	0	0
23	0	0		0			0			-			Dropped																		
24	0	0		0			0			0			0			0			0			0						0	0	0	0
25	0	0		0			0			0			0			0			0			0						0	0	0	0
26	0	0		0			0			0			0			0			0			0						0	0	0	0
27	0	0		0			0			0			0			0			0			0						0	0	0	0
28	0	0		0			0			0			0			0			-			*0			0			0	0	0	0
29	0	0		0			0			-			*0			0			0			0			0			0	0	0	0
30	0	LO		0			0			0			0			0			0			0						0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

N9G = No ninth grade

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1A. Group total reaction scores following the application of test material.
Sample: A (MINERAL OIL)

	Application Number																								Challenge			
	1	2		3			4			5			6			7			8			9			MU						
Scores	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
0	28	29	0	30	0	0	30	0	0	28	0	0	28	0	0	29	0	0	26	0	0	26	0	0	3	0	0	28	28	28	28
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	28	29	0	30	0	0	30	0	0	28	0	0	28	0	0	29	0	0	27	0	0	26	0	0	3	0	0	28	28	28	28
Drop	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	0	2	2	2	2
N9G	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
*	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
X	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	2	1	0	0	0	0	0	0	0	2	0	0	2	0	0	1	0	0	3	0	0	4	0	0	0	0	0	2	2	2	2
Grand Total	30	30		30			30			30			30			30			30			30			3			30	30	30	30
E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Letter Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site

N9G = No ninth grade

O',A' = second scoring of challenge sites (96 hours)

W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1B. Individual reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

Subject	Application Number 1	2		3			4			5			6			7			8			9			MU			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	C	M	M1	O	A	O'	A'
1	0	0		0			0			0			0			0			0			0						0	0	0	0
2	0	0		0			0			0			0			0			0			0						0	0	0	0
3	0	0		0			0			0			0			0			0			0						0	0	0	0
4	0	0		0			0			0			0			0			0			0						0	0	0	0
5	0	0		0			0			0			0			0			0			0						0	0	0	0
6	0	0		0			0			0			0			0			0			0						0	0	0	0
7	0	0		0			0			0			0			0			0			0						0	0	0	0
8	0	0		0			0			0			0			0			0			0						0	0	0	0
9	LO	0		0			0			0			0			0			0			0						0	0	0	0
10	0	0		0			0			0			0			0			0			0						0	0	0	0
11	0	0		0			0			0			0			0			0			0						0	0	0	0
12	0	0		0			0			0			0			0			0			0						0	0	0	0
13	0	0		0			0			0			0			0			0			0						0	0	0	0
14	0	0		0			0			0			0			0			0			0						0	0	0	0
15	0	0		0			0			0			0			0			0			0						0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1B. Group total reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

	Application Number																										Challenge			
	1	2		3			4			5			6			7			8			9			MU						
Scores	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
0	14	15	0	15	0	0	15	0	0	15	0	0	15	0	0	15	0	0	15	0	0	15	0	0	0	0	0	15	15	15	15
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	14	15	0	15	0	0	15	0	0	15	0	0	15	0	0	15	0	0	15	0	0	15	0	0	0	0	0	15	15	15	15
Drop	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
X	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grand Total	15	15		15			15			15			15			15			15			15			0			15	15	15	15
E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Letter Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site

O',A' = second scoring of challenge sites (96 hours)

W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1C. Individual reaction scores following the application of test material.
Sample: C (50% in Mineral Oil SP-7053 in Finished Oil)

Subject Number	Application Number 1	2	3	4	5	6	7	8	9	MU	Challenge			
	O	O M	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O	A	O'	A'
16	0	0	0	0	0	0	0	0	0		0	0	0	0
17	0	0	0	0	0	0	0	0	0		0	0	0	0
18	0	0	0	0	0	0	0	0	0		0	0	0	0
19	0	0	0	0	0	0	0	-	*0	0	0	0	0	0
20	L0	0	0	L0	0	0	0	0	0		0	0	0	0
21	0	0	0	0	0	0	0	0	N9G		Dropped			
22	0	0	0	0	0	0	0	0	0		0	0	0	0
23	0	0	0	0	-	Dropped								
24	0	0	0	0	0	0	0	0	0		0	0	0	0
25	0	0	0	0	0	0	0	0	0		0	0	0	0
26	0	0	0	0	0	0	0	0	0		0	0	0	0
27	0	0	0	0	0	0	0	0	0		0	0	0	0
28	0	0	0	0	0	0	0	-	*0	0	0	0	0	0
29	0	0	0	0	-	*0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0		0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

N9G = No ninth grade

Table 1C. Group total reaction scores following the application of test material.
Sample: C (50% in Mineral Oil SP-7053 in Finished Oil)

	Application Number																								Challenge			
	1	2		3			4			5			6			7			8			9			MU						
Scores	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
0	14	15	0	15	0	0	14	0	0	13	0	0	13	0	0	14	0	0	12	0	0	11	0	0	3	0	0	13	13	13	13
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	14	15	0	15	0	0	14	0	0	13	0	0	13	0	0	14	0	0	12	0	0	11	0	0	3	0	0	13	13	13	13
Drop	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	0	2	2	2	2
N9G	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
*	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
X	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	1	0	0	0	0	0	1	0	0	2	0	0	2	0	0	1	0	0	3	0	0	4	0	0	0	0	0	2	2	2	2
Grand Total	15	15		15			15			15			15			15			15			15			3			15	15	15	15
E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Letter Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site

N9G = No ninth grade

O',A' = second scoring of challenge sites (96 hours)

W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1A. Individual reaction scores following the application of test material.
Sample: A (MINERAL OIL)

Subject	Application Number 1	2		3			4			5			6			7			8			9			MU			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
31	0	0		0			0			0			0			0			0			0						NP	0	NP	0
32	0	0		0			0			0			0			0			0			0						0	0	0	0
33	0	0		0			0			0			0			0			0			0						0	0	0	0
34	0	0		0			0			0			0			0			0			0						0	0	0	0
35	0	0		0			0			0			0			0			0			0						0	0	0	0
36	0	0		0			0			0			0			0			0			0						0	0	0	0
37	0	0		0			-			*0			0			0			0			0			0			0	0	0	0
38	0	0		0			0			0			0			0			0			-			*0			0	0	0	0
39	0	0		0			0			0			0			0			0			0						0	0	0	0
40	-	Dropped																													
41	0	0		0			0			0			0			0			0			0						0	0	0	0
42	0	0		0			0			0			0			0			0			0						0	0	0	0
43	0	0		0			0			0			0			0			0			0						0	0	0	0
44	0	0		0			0			0			0			0			0			0						0	0	0	0
45	0	0		0			0			-			*0			0			0			0			0			0	0	0	0
46	0	0		0			0			0			0			0			0			0						0	0	0	0
47	0	0		0			0			0			0			0			0			0						0	0	0	0
48	0	0		0			0			0			0			0			-			*0			0			0	0	0	0
49	0	0		0			0			0			0			0			0			0						0	0	0	0
50	0	0		0			0			0			0			0			0			0						0	0	0	0
51	0	-		0			0			Dropped																					
52	0	0		0			0			0			0			0			0			0						0	0	0	0
53	0	0		0			0			0			0			0			0			0						0	0	0	0
54	0	0		0			0			0			0			0			0			0						0	0	0	0
55	0	0		0			0			0			0			0			0			0						0	0	0	0
56	0	0		0			0			0			0			0			0			0						0	0	0	0
57	0	0		0			0			0			-			*0			0			0			0			0	0	0	0
58	0	0		0			0			0			0			-			*0			0			0			0	0	0	0
59	0	0		0			0			0			0			0			0			0						0	0	0	0
60	0	0		0			0			0			0			0			-			*0			0			0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
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E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

NP = Not patched

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1A. Individual reaction scores following the application of test material.
Sample: A (MINERAL OIL)

Subject	Application Number 1	2	3	4	5	6	7	8	9	MU	Challenge			
Number	O	O M	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O	A	O'	A'
61	0	0	0	0	-	*0	0	0	0	N9G	0	0	0	0
62	0	0	0	0	0	0	0	0	0		0	0	0	0
63	0	0	-	*0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0		0	0	0	0
65	0	0	0	0	0	0	0	0	0		0	0	0	0
66	0	0	0	0	0	0	0	0	0		0	0	0	0
67	Dropped													
68	0	0	0	0	-	*0	0	0	0	Dropped				
69	0	0	0	0	0	0	0	0	0		0	0	0	0
70	0	0	0	0	0	0	0	0	0		0	0	0	0
71	0	0	0	Dropped										
72	0	0	0	0	0	0	0	0	0		0	0	0	0
73	0	0	0	0	0	0	0	0	0		0	0	0	0
74	0	0	0	0	0	0	0	0	0		0	0	0	0
75	0	0	0	0	0	0	0	0	0		0	0	0	0
76	0	0	0	0	0	0	0	0	0		0	0	0	0
77	0	0	0	0	0	0	0	0	0		0	0	0	0
78	0	0	0	0	0	0	0	0	0		0	0	0	0
79	0	0	0	0	0	0	0	0	0		0	0	0	0
80	0	0	0	0	0	0	0	0	0		0	0	0	0
81	Dropped													
82	0	0	0	0	0	0	0	0	0		0	0	0	0
83	0	0	0	0	0	0	0	0	0		0	0	0	0
84	0	0	0	0	0	0	0	0	0		0	0	0	0
85	0	0	0	0	0	0	0	0	0		0	0	0	0
86	0	0	0	0	0	0	0	0	0		0	0	0	0
87	LO	0	0	0	0	0	0	-	*0	0	0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
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B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

N9G = No ninth grade

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

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L = Test patch lost soon after application (Not included in score totals)
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R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1A. Individual reaction scores following the application of test material.
Sample: A (MINERAL OIL)

Subject	Application Number 1	2		3			4			5			6			7			8			9			MU			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
88	0	0		0			0			0			0			0			0			0						0	0	0	0
89	0	0		0			0			0			0			0			0			0						0	0	0	0
90	0	0		0			0			0			0			0			0			0						0	0	0	0
91	0	0		0			0			0			0			0			0			0						0	0	0	0
92	0	0		0			0			0			0			0			0			0						0	0	0	0
93	0	0		0			0			0			0			0			0			0						0	0	0	0
94	0	0		0			0			0			0			0			0			0						0	0	0	0
95	0	-		*0			0			0			0			0			0			0			0			0	0	0	0
96	0	0		0			0			0			0			0			*0			0			N9G			Dropped			
97	0	0		0			0			0			0			-			-			*0			0			Dropped			
98	0	0		0			0			0			0			0			0			0						0	0	0	0
99	0	0		0			0			0			0			0			0			0						0	0	0	0
100	0	0		0			0			0			0			0			0			0						0	0	0	0
101	0	0		0			0			0			0			0			0			0						0	0	0	0
102	0	0		0			0			0			0			0			0			0						0	0	0	0
103	0	0		0			0			0			0			0			0			0						0	0	0	0
104	0	0		0			0			0			0			0			0			0						Dropped			
105	0	0		-			*0			Dropped																					
106	-	Dropped																													
107	0	0		0			0			0			0			0			0			0						0	0	0	0
108	-	Dropped																													
109	0	0		0			0			0			0			0			0			0						0	0	0	0
110	0	0		0			0			0			0			0			0			-			*0			0	0	0	0
111	0	0		0			0			0			0			0			0			0						0	0	0	0
112	0	0		0			0			0			0			0			0			0						0	0	0	0
113	0	0		0			0			0			0			0			0			0						0	0	0	0
114	0	0		0			0			0			0			0			0			0						0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
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P = Papules - red, solid, pinpoint elevations, granular feeling
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B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

N9G = No ninth grade

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1A. Individual reaction scores following the application of test material.
Sample: A (MINERAL OIL)

Subject	Application Number 1	2		3			4			5			6			7			8			9			Mu			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
115	0	0		0			0			0			0			0			0			0						0	0	0	0
116	-	Dropped																													
117	0	0		0			0			0			0			0			0			0						0	0	0	0
118	0	0		0			0			0			0			0			0			-			*0			0	0	0	0
119	0	0		0			0			0			0			0			0			0						0	0	0	0
120	LO	0		0			0			0			0			0			0			0						0	0	0	0
121	0	-		Dropped																											
122	0	0		0			0			0			0			0			0			0						0	0	0	0
123	0	0		0			0			0			0			0			0			0						0	0	0	0
124	0	0		0			0			0			0			0			0			N9G						0	0	0	0
125	0	0		0			0			0			0			0			0			0						0	0	0	0
126	0	0		0			0			0			0			0			0			C						Dropped			
127	0	0		0			0			0			0			0			-			*0			0			0	0	0	0
128	0	0		0			0			0			-			*0			0			0			0			0	0	0	0
129	0	0		0			0			-			Dropped																		
130	0	0		0			0			0			0			0			0			0						0	0	0	0
131	0	0		0			0			0			0			0			-			*0			N9G			0	0	0	0
132	0	0		0			0			0			0			0			0			0						0	0	0	0
133	0	0		0			0			0			0			0			0			0						0	0	0	0
134	0	0		0			0			0			0			0			0			N9G						Dropped			
135	0	0		0			0			0			0			0			0			0						0	0	0	0
136	0	0		0			0			0			0			0			0			0						0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
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* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
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R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1A. Group total reaction scores following the application of test material.
Sample: A (MINERAL OIL)

	Application Number																										Challenge			
	1	2		3			4			5			6			7			8			9			MU					
Scores	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
0	98	97	0	96	0	0	95	0	0	91	0	0	91	0	0	92	0	0	86	0	0	83	0	0	12	0	0	88	89	88	89
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	98	97	0	96	0	0	95	0	0	91	0	0	91	0	0	92	0	0	86	0	0	83	0	0	12	0	0	88	89	88	89
Drop	2	6	0	7	0	0	8	0	0	10	0	0	11	0	0	11	0	0	11	0	0	11	0	0	1	0	0	17	17	17	17
N9G	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	3	0	0	0	0	0	0
-	4	3	0	2	0	0	1	0	0	4	0	0	1	0	0	2	0	0	7	0	0	3	0	0	0	0	0	0	0	0	0
*	0	0	0	1	0	0	2	0	0	1	0	0	3	0	0	1	0	0	2	0	0	7	0	0	3	0	0	0	0	0	0
X	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Sub Total	8	9	0	10	0	0	11	0	0	15	0	0	15	0	0	14	0	0	20	0	0	23	0	0	7	0	0	18	17	18	17
Grand Total	106	106		106			106			106			106			106			106			106			19			106	106	106	106
E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
W	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Letter Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

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N9G = No ninth grade

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L = Test patch lost soon after application (Not included in score totals)
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XR = Patch omitted for reasons unrelated to the test
NP = Not patched

Table 1B. Individual reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

Subject	Application Number 1	2		3			4			5			6			7			8			9			MU			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
31	0	0		0			0			0			0			0			0			0						NP	0	NP	1PS
32	0	0		0			0			0			0			0			0			0						0	0	0	0
33	0	0		0			0			0			0			0			0			0						0	0	0	0
34	0	0		0			0			0			0			0			0			0						0	0	0	0
35	0	0		0			0			0			0			0			0			0						0	0	0	0
36	0	0		0			0			0			0			0			0			0						0	0	0	0
37	0	0		0			-			*0			0			0			0			0			0			0	0	0	0
38	0	0		0			0			0			0			0			0			-			*0			0	0	0	0
39	0	0		0			0			0			0			0			0			0						0	0	0	0
40	-	Dropped																													
41	0	0		0			0			0			0			0			0			0						0	0	0	0
42	0	0		0			0			0			0			0			0			0						0	0	0	0
43	0	0		0			0			0			0			0			0			0						0	0	0	0
44	0	0		0			0			0			0			0			0			0						0	0	0	0
45	0	0		0			0			-			*0			0			0			0			0			0	0	0	0
46	0	0		0			0			0			0			0			0			0						0	0	0	0
47	0	0		0			0			0			0			0			0			0						0	0	0	0
48	0	0		0			0			0			0			-			*0			0			0			0	0	0	0
49	0	0		0			0			0			0			0			0			0						0	0	0	0
50	0	0		0			0			0			0			0			0			0						0	0	0	0
51	0	-		0			0			Dropped																					
52	0	0		0			0			0			0			0			0			0						0	0	0	0
53	0	0		0			0			0			0			0			0			0						0	0	0	0
54	0	0		0			0			0			0			0			0			0						0	0	0	0
55	0	0		0			0			0			0			0			0			0						0	0	0	0
56	0	0		0			0			0			0			0			0			0						0	0	0	0
57	0	0		0			0			0			0			-			*0			0			0			0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)

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Table 1B. Individual reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

Subject Number	Application Number 1	2	3	4	5	6	7	8	9	MU	Challenge			
	O	O M	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O	A	O'	A'
58	0	0	0	0	0	0	0	-	*0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0		0	0	0	0
60	0	0	0	0	0	0	0	-	*0	0	0	0	0	0
61	0	0	0	0	-	*0	0	0	0	N9G	0	0	0	0
62	0	0	0	0	0	0	0	0	0		0	0	0	0
63	0	0	-	*0	0	0	0	0	C	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0		0	0	0	0
65	0	0	0	0	0	0	0	0	0		0	0	0	0
66	0	0	0	0	0	0	0	0	0		0	0	0	0
67	Dropped													
68	0	0	0	0	-	*0	0	0	0	Dropped				
69	0	0	0	0	0	0	0	0	0		0	0	0	0
70	0	0	0	0	0	0	0	0	0		0	0	0	0
71	0	0	0	Dropped										
72	0	0	0	0	0	0	0	0	0		0	0	0	0
73	0	0	0	0	0	0	0	0	0		0	0	0	0
74	0	0	0	0	0	0	0	0	0		0	0	0	0
75	0	0	0	0	0	0	0	0	0		0	0	0	0
76	-	0	0	0	0	0	0	0	0		0	0	0	0
77	0	0	0	0	0	0	0	0	0		0	0	0	0
78	0	0	0	0	0	0	0	0	0		0	0	0	0
79	0	1	1	0	0	0	0	1	0		0	0	0	0
80	0	0	0	0	0	0	0	0	0		0	0	0	0
81	Dropped													
82	0	0	0	0	0	0	0	0	0		0	0	0	0
83	0	0	0	0	0	0	0	0	0		0	0	0	0
84	0	0	0	0	0	0	0	0	0		0	0	0	0

O = original site; M = first moved site; M1 = second moved site
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Table 1B. Individual reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

Subject Number	Application Number 1	2	3	4	5	6	7	8	9	MU	Challenge
	O	O M	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O M M1	O A O' A'
85	0	0	0	0	0	0	0	0	0		0 0 0 0
86	0	0	0	0	0	0	0	0	0		0 0 0 0
87	L0	0	0	0	0	0	0	-	*0	0	0 0 0 0
88	0	0	0	0	0	0	0	0	0		0 0 0 0
89	0	0	0	0	0	0	0	0	0		0 0 0 0
90	0	0	0	0	0	0	0	0	0		0 0 0 0
91	0	0	0	0	0	0	0	0	0		0 0 0 0
92	0	0	0	0	0	0	0	0	0		0 0 0 0
93	0	0	0	0	0	0	0	0	0		0 0 0 0
94	0	0	0	0	0	0	0	0	0		0 0 0 0
95	0	-	*0	0	0	0	0	0	0	0	0 0 0 0
96	0	0	0	0	0	0	0	0	0		0 0 0 0
97	0	0	0	0	0	0	-	*0	0	N9G	Dropped
98	0	0	0	0	0	0	0	-	*0	0	Dropped
99	0	0	0	0	0	0	0	0	0		0 0 0 0
100	0	0	0	0	0	0	0	0	0		0 0 0 0
101	0	0	0	0	0	0	0	0	0		0 0 0 0
102	0	0	0	0	0	0	0	0	0		0 0 0 0
103	0	0	0	0	0	0	0	0	0		0 0 0 0
104	0	0	0	0	0	0	0	0	0		Dropped
105	0	0	-	*0	Dropped						
106	-	Dropped									
107	0	0	0	0	0	0	0	0	0		0 0 0 0
108	-	Dropped									
109	0	0	0	0	0	0	0	0	0		0 0 0 0
110	0	0	0	0	0	0	0	0	-	*0	0 0 0 0
111	0	0	0	0	0	0	0	0	0		0 0 0 0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

N9G = No ninth grade

Table 1B. Individual reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

Subject	Application Number 1	2		3			4			5			6			7			8			9			MU			Challenge			
Number	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
112	0	0		0			0			0			0			0			0			0						0	0	0	0
113	0	0		0			0			0			0			0			0			0						0	0	0	0
114	0	0		0			0			0			0			0			0			0						0	0	0	0
115	0	0		0			0			0			0			0			0			0						0	0	0	0
116	-	Dropped																													
117	0	0		0			0			0			0			0			0			0						0	0	0	0
118	0	0		0			0			0			0			0			0			-			*0			0	0	0	0
119	0	0		0			0			0			0			0			0			0						0	0	0	0
120	LO	0		0			0			0			0			0			0			0						0	0	0	0
121	0	-		Dropped																											
122	0	0		0			0			0			0			0			0			0						0	0	0	0
123	0	0		0			0			0			0			0			0			0						0	0	0	0
124	0	0		0			0			0			0			0			0			N9G						0	0	0	0
125	0	0		0			0			0			0			0			0			0						0	0	0	0
126	0	0		0			0			0			0			0			0			0						Dropped			
127	0	0		0			0			0			0			0			-			*0			0			0	0	0	0
128	0	0		0			0			-			*0			0			0			0			0			0	0	0	0
129	0	0		0			-			Dropped																					
130	0	0		0			0			0			0			0			0			0						0	0	0	0
131	0	0		0			0			0			0			0			-			*0			N9G			0	0	0	0
132	0	0		0			0			0			0			0			0			0						0	0	0	0
133	0	0		0			0			0			0			0			0			0						0	0	0	0
134	0	0		0			0			0			0			0			0			N9G						Dropped			
135	0	0		0			0			0			0			0			0			0						0	0	0	0
136	0	0		0			0			0			0			0			0			0						0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similat to a sunburn)
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B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading - evidence of the reaction beyond the test site
W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

N9G = No ninth grade

g = Glazing
y = Peeling
c = Scab, dried film of serous exudate of vesicular or bulla reaction
d = Hyperpigmentation (reddish-brown discoloration of test site)
h = Hypopigmentation (loss of visible pigmentation at test site)
f = Fissuring - grooves in the superficial layers of the skin

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test

Table 1B. Group total reaction scores following the application of test material.
Sample: B (SP-7053 in Finished Oil)

	Application Number																										Challenge			
	1	2		3			4			5			6			7			8			9			MU					
Scores	O	O	M	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	M	M1	O	A	O'	A'
0	98	96	0	95	0	0	95	0	0	91	0	0	91	0	0	92	0	0	85	0	0	83	0	0	12	0	0	88	89	88	88
1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub Total	98	97	0	96	0	0	95	0	0	91	0	0	91	0	0	92	0	0	86	0	0	83	0	0	12	0	0	88	89	88	89
Drop	2	6	0	7	0	0	8	0	0	10	0	0	11	0	0	11	0	0	11	0	0	11	0	0	1	0	0	17	17	17	17
N9G	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	3	0	0	0	0	0	0
-	4	3	0	2	0	0	1	0	0	4	0	0	1	0	0	2	0	0	7	0	0	3	0	0	0	0	0	0	0	0	0
*	0	0	0	1	0	0	2	0	0	1	0	0	3	0	0	1	0	0	2	0	0	7	0	0	3	0	0	0	0	0	0
X	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Sub Total	8	9	0	10	0	0	11	0	0	15	0	0	15	0	0	14	0	0	20	0	0	23	0	0	7	0	0	18	17	18	17
Grand Total	106	106		106			106			106			106			106			106			106			19			106	106	106	106
E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
W	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Letter Totals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
R	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

O = original site; M = first moved site; M1 = second moved site
O,A = first scoring of original and adjacent challenge sites (48 hours)
O',A' = second scoring of challenge sites (96 hours)

0 = No visible reaction and/or erythema
1 = Mild reaction - macular erythema (faint, but definite pink)
2 = Moderate reaction - macular erythema (definite redness, similar to a sunburn)
3 = Strong to severe reaction - macular erythema (very intense redness)

E = Edema - swelling, spongy feeling when palpated
P = Papules - red, solid, pinpoint elevations, granular feeling
V = Vesicles - small elevation containing serous fluid (blister-like), diameter 5mm or less
B = Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter
S = Spreading evidence of the reaction beyond the test site
N9G = No ninth grade

W = Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I = Induration - solid, elevated, hardened, thickening

- = Absence
* = Residual reaction to earlier application after absence (Not included in totals)
L = Test patch lost soon after application (Not included in score totals)
X = Patch omitted due to previous strong test reaction(s)
R = Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions
XR = Patch omitted for reasons unrelated to the test
NP = Not patched

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APPENDIX II

(Total number of pages = 1)

Deviations

The following is a list of deviations concerning the length of time the patch was in contact with the skin:

Subject Number	Application Number	Test Article	Approximate Hours of Contact
9	1	A,B	9
20	1	A,C	22
87	1	A	12
87	1	B	4
120	1	A,B	5.50
30	2	A	Unknown
110	2	A,C	29
20	4	C	22
14	5	A,B	40

Subject Nos. 21, 61, 97, 131, and 134 received nine induction applications, but only eight skin evaluations.

Due to technician error, Subject No. 127 did not have second pregnancy test on October 3, 1994.

Due to technician error, Documentation of Non-Pregnancy was not written down on October 3, 1994. The test results were verified on the following day from thé urine and the test kits. The results were recorded at this time.

APPENDIX III

(Total number of pages = 1)

Subjects Failing to Complete

Those subjects who did not complete the study and the reasons why are listed below:

Subject Number	Reason
21	Child hospitalized
23	Work schedule changed
40, 106, 108	Failed to return
51, 105, 116, 121, 129	Missed two induction applications
67	No transportation
68	Pregnant
71	Went back to school
81	Got a job
98, 126, 134	Missed challenge application
97, 104	Missed challenge evaluation

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APPENDIX IV

(Total number of pages =1)

Institutional Review Board Approval

INSTITUTIONAL REVIEW BOARD
OF
HILL TOP RESEARCH, INC.

Robert H. McMaster, M.D., Chairman

PROJ. No. HN-1399-70
PAGE No. E 9

July 12, 1994

Robert A. Harper, Ph.D.
Hill Top Research, Inc.
Main and Mill Streets
Miamiville, OH 45147

Ref: 94-1399-70
Title: REPEATED INSULT PATCH TEST WITH
(Modified Draize Procedure)
Sponsor: Chevron Research and Technology Company

Dear Dr. Harper:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above captioned study. Any modifications required for this approval are shown below. The review was carried out by core members.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or any new advertisements. Serious adverse reactions must be reported promptly to the IRB. Progress reports on the research activity are to be submitted every four months.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR Section 21, Parts 50 and 56.

Sincerely,

Robert H. McMaster M.D.

Robert H. McMaster, M.D.
Chairman

Date 7/12/94

RHM/sll

Modifications: None required.

APPENDIX V

(Total number of pages = 26)

Protocol, Protocol Amendments and Consent Form

Ref.: 94-1399-70

REPEATED INSULT PATCH TEST WITH N FINISHED OIL (Modified Draize Procedure)

OBJECTIVE

To evaluate finished Oil) for the induction of contact sensitization by repetitive applications to the skin of human volunteers and to report any irritation observed with the test material.

SPONSOR AND MONITOR

INVESTIGATIVE ORGANIZATION, TEST LOCATION AND PERSONNEL

Organization:	Hill Top Research, Inc.
Test Location:	Miamiville, Ohio
Investigator:	Robert A. Harper, Ph.D.
Test Area Supervisor:	Grace E. Kenney, M.S.
Senior Project Leader:	Bonnie Rue

CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, will be reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board must be obtained prior to the initiation of the investigation.

A properly executed informed consent document in compliance with FDA regulations (21 CFR 50) will be obtained from each subject prior to entering the study.

HILL TOP RESEARCH, INC.
P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/831-1217
The Hill Top Companies
Hill Top Research, Inc. • Hill Top Pharmatest, Inc. • Hill Top Biolabs, Inc.

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EXPERIMENTAL DESIGN

The design is an adaptation of the Draize Patch Test.[1] The test of each article consists of the following:

A. INDUCTION PERIOD - Repetitive application of test article to the same site on the skin for approximately three weeks. (Alternate sites are used if test articles evoke irritation under conditions of the test.)

B. REST PERIOD - Following the induction period, the subjects do not receive any application of test article for approximately two weeks.

C. CHALLENGE - Application of test article to a pre-exposed and a naive site to test for reactions indicative of contact sensitization.

D. RECHALLENGE - Application of test article or test article components to naive site to confirm reactions indicative of contact sensitization.

TEST ARTICLES

The Sponsor will furnish the undiluted test article(s) and stipulate each test concentration.

Hill Top Research, Inc. will supply the negative control (Mineral Oil U.S.P.) and all other materials required for the test.

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[1]J. H. Draize, "Dermal Toxicity," in Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, The Staff of the Division of Pharmacology of the Federal Food and Drug Administration (Austin, Texas: The Editorial Committee of the Association of Food and Drug Officials of The United States, 1959), pg. 52

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TEST ARTICLES (Continued)

Hill Top Lab Code	Sponsor's Code	Patch Type*	Test As	Method and Quantity of Application to Patch
A	Mineral Oil U.S.P.	*	Received	0.1ml by pipette or syringe
B	[illegible] Oil)	*	Received	0.1ml by pipette or syringe
C	[illegible] Oil)	*	50% in Mineral Oil U.S.P.	0.1ml by pipette or syringe

*Semi-occluded using Webril® pads (Professional Medical Products, Inc.) secured on two opposing sides with hypoallergenic tape (Blenderm®).

**If additional dose concentrations need to be evaluated, an amendment to the protocol shall be written to include all additional procedures.

A 20g sample of the test article will be returned to the Study Monitor for archiving. All remaining test article and remaining dosing mixture(s) (if the test article is administered as a dilution during the main part of the induction phase and/or challenge phase) shall be shipped to the Sponsor upon acceptance of the final report. The sample container will be labeled with the test article name, Sponsor's protocol number, and the Testing Laboratory's study number. Each test article shall be accompanied by a transmittal letter describing the sample contained in the shipment. The test article shall be packed in a suitable container. The sample shall be

telephone [illegible] of shipping by [illegible]ification shall include test article and study identification, carrier, waybill number, and estimated time of arrival.

TEST ARTICLES (Continued)

Application of any of these concentrations will be halted if, in the judgement of the Investigator, irritation production is too great to allow detection of a sensitization response at challenge.

STUDY POPULATION

A sufficient number of healthy adult male/female subjects will be enrolled to ensure a minimum of 20 subjects complete the study. The subjects will be required to give written informed consent and to complete a brief demographic/medical questionnaire before taking part in the study. The investigative staff are to exclude volunteers from entrance into the study for any of the following reasons:

- Insulin-dependent diabetes.
- Mastectomy for cancer involving removal of lymph nodes within the past year.
- Active clinically significant skin diseases which may contraindicate participation, including eczema and atopic dermatitis.
- Participation in any patch test for irritation or sensitization within the last four weeks.
- Routine high dosage use of anti-inflammatory drugs (aspirin, ibuprofen, corticosteroids), immunosuppressive drugs or antihistamine medications (steroid nose drops and/or eye drops are permitted).
- Severe asthma.
- Immunological disorders such as HIV positive, AIDS and systemic lupus erythematosus.
- Use of topical drugs at patching site.
- Pregnant or lactating women.
- Known sensitivity to lubricant oils or products.
- Daily exposure to lubricant oils or products.
- Known allergy to detergents, sulfa containing products, or sulfonates.

No demographic profile is specified by protocol, except that each subject must be 21-60 years of age.

Anyone who is absent more than once during the induction phase or at any time during the challenge week will be withdrawn from further participation in the study. Subjects failing to complete the study will be identified and, whenever possible, a reason will be given.

TREATMENT ASSIGNMENTS

Each subject will test either Test Article B or C and the negative control (Test Article A). A total of two test areas are available for application of the test kit to the deltoid region of the upper arm. Each test area is functionally subdivided into four individual patch sites: the original (O), move (M and M-1) and challenge patch (A) application sites. Each area is assigned as a block of four horizontally arranged contiguous sites on the surface of the skin (an overall area of approximately 4 1/2cm by 22cm).

The assignment of the two test areas to individual test articles within the test kit will be rotated sequentially within the panel. During induction, test articles will be repeatedly applied to the same test area on each subject. Within each test area, the individual test articles will be repetitively applied to the same site if the test article is well tolerated.

PROCEDURE

The test kit for each subject will contain one test article and one control test article. Each test day, patches will be prepared fresh according to the specifications presented in the TEST ARTICLES section. All patches will be applied by the laboratory staff but removed by the individual subject.

Each test article in the test kit will be applied to sites on the skin of the deltoid region of the upper arm for a contact period of 24 ± 1 hours per application. Induction applications will be made three times per week (on Monday, Wednesday and Friday) for three successive weeks. The nine applications made during these three weeks will be termed Induction Application Nos. 1 through 9, respectively. During the fourth week (on Monday), any subject who is absent for one of the regularly scheduled induction applications will receive a make-up induction application.

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PROCEDURE (Continued)

All induction applications for an individual test article will be made to the same site (the site receiving the original test article at Induction Application No. 1) unless reactions become so strong as to make this inadvisable. Assessment of a score of Grade 2 or greater is considered to be a strong reaction. In this case, subsequent applications of the offending test article will be made to an adjacent area, and a second change of site will be made if a second strong reaction occurs. If a third strong reaction to the test article is manifested, patches of this test article will be discontinued until after the rest period has been completed. The use of a first and second adjacent site will be identified on the source document as M and M-1 sites, respectively, to indicate movement of test site from the original (O) application site.

A 10 to 17-day rest period will follow the final induction application. Following the rest period, on Monday of the sixth week, a challenge application of the test article(s) in the test kit will be made to each subject. During the challenge application, the test articles will remain in contact with the skin for a period of 24 ± 1 hours. Challenge will consist of application to a naive site located away from the original (O) application site (e.g., opposite arm or opposite side of the back). Simultaneous application to a pre-exposed site (i.e., the original site used for Induction Application No. 1) will be made concurrently with the challenge at a naive site. If the presence of a residual reaction at any of the induction sites makes application of the challenge patch to an adjacent naive site inadvisable, an alternate naive site on the deltoid region of the upper arm may be used and is documented in the test records and the report.

Observations at a naive site will provide a basis for an interpretation of contact sensitization. Data obtained from the challenge patch applied to a pre-exposed site will be reported and used to support the conclusions drawn from observations at the naive site. Positive reactions at a pre-exposed site will not be interpreted as significant evidence of contact sensitization unless confirmed by observations at a naive site.

EVALUATIONS

Reactions will be scored Monday, Wednesday and Friday, 48 or 72 hours after each induction application (24 or 48 hours after patch removal); 48 hours and 96 hours after challenge application (24 and 72 hours after patch removal).

Skin responses to each patch application will be examined and graded under light supplied by a 100-watt incandescent blue bulb. On any group of subjects, the same scorer will carry out all evaluations of the test sites. All reasonable attempts will be made to ensure that the same individual will do all scoring of test sites during the course of the study. The scorer will be blinded as to the treatment assignments. Reactions to the test articles are to be documented on the source document by the numerical and letter grade scoring system defined in this protocol (See attached Scoring Scale). In instances where a strong reaction warrants application of the test article to the M or M-1 site, residual scores will be recorded through to the end of the study for all previously exposed sites.

ADVERSE EVENT/PATCH SITE DEFINITION

An adverse event is any unusual or unexpected reaction that occurs during the study. The subject, under the direction of the Investigator (or designee), is referred to Hill Top's Consultant Physician for treatment. All adverse events are monitored by the Hill Top Staff until resolution.

REPORT

The final report will identify the number of subjects completing the study and summarize the data and conclusions relative to observations made with these subjects. Source data will be retained by Hill Top Research, Inc. on microfilm. All raw data and the original final report will be returned to the Sponsor.

A copy of the original source data will be maintained according to the Investigators standard operating procedure. Copies of transcribed typed data tables will be incorporated into the final report as data tables along with but not limited to the following:

(a) A summary that includes a brief description of the methods and highlights all positive findings and any deviations from control data that may be indicative of toxic effects.

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REPORT (Continued)

(b) A Quality Assurance Statement, including inspection dates of critical phases of the study, signed by the Testing Laboratory's Quality Assurance Unit.

(c) Name and address of the Testing Laboratory and names and signatures of all responsible personnel.

(d) A methods section including a complete description of: test article; data evaluation; test system; test article preparation and administration; scoring; statistical methods; dates of study initiation (date of Investigator's signature), experimental start and termination dates; procedures for the storage of raw data final report, and a retain sample of the test article.

(e) A results section including a discussion of evaluation of test results.

(f) The final report appendices will include a copy of the protocol, all protocol amendments, and a list of all protocol deviations and their effect on the outcome of the study.

NOTICE

No modifications of the protocol will be permitted without the written approval from the Sponsor, the IRB Chairman and the Investigator. Such changes must be documented in writing as soon as possible in the form of any amendment that is to be attached to the final protocol. In the event and immediate alteration to the protocol is required, the change shall be made and documented by the Investigator after seeking verbal approval from the Sponsor, the IRB Chairman and the Investigator. Written approval in the form of an amendment to the protocol will follow and be attached to the final protocol.

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PROTOCOL APPROVAL

HILL TOP RESEARCH, INC.

Principal Investigator:

Robert A. Harper 6/30/94

Robert A. Harper, Ph.D. Date

General Manager:

Ralph Anderson 6/30/94

Ralph Anderson Date

Sponsor's Monitor/Representative:

ref.: \patch\projects\941399.pro

SCORING SCALE AND DEFINITION OF SYMBOLS USED IN TABULATING DATA

Reactions to the test materials are scored according to the following scale.

Each of the scores represents the presence of a clinically significant characteristic localized in a representative portion of the patch area, that is 25% or more of the patch site. Questionable (barely perceptible, minimal or involving less than 25% of the patch site) reactions are inconclusive and are not recorded except in diary format (the latter is furnished at the discretion of the patch scorer).

0	=	No visible reaction and/or erythema
1	=	Mild reaction - macular erythema (faint, but definite pink)
2	=	Moderate reaction - macular erythema (definite redness, similar to a sunburn)
3	=	Strong to severe reaction - macular erythema (very intense redness)

Definition of letter grades appended to a numerical grade:

E	=	Edema - swelling, spongy feeling when palpated
P	=	Papules - red, solid, pinpoint elevations, granular feeling like, diameter 5mm or less
V	=	Vesicles - small elevation containing serous fluid (blister-like), diameter 5 mm or less
B	=	Bulla reaction - fluid-filled lesion greater than 5mm in diameter
S	=	Spreading - evidence of the reaction beyond the Webril® pad area
W	=	Weeping - result of a vesicular or bulla reaction - serous exudate - clear fluid oozing or covering patch site
I	=	Induration - solid, elevated, hardened, thickening skin reaction

Definition of superficial observations appended to a numerical and/or letter grade:

g	=	Glazing
y	=	Peeling
c	=	Scab, dried film of serous exudate of vesicular or bulla reaction
d	=	Hyperpigmentation (reddish-brown discoloration of test site)
h	=	Hypopigmentation (loss of visible pigmentation at test site)
f	=	Fissuring - grooves in the superficial layers of the skin
(C)	=	Additional comments appear below or on the following page

Applications must either be terminated or moved to naive adjacent sites if a score of Grade 2 or greater is observed.

SCORING SCALE AND DEFINITION OF SYMBOLS USED IN TABULATING DATA (Continued)

Symbols used in tabulating data (in addition to scoring grades):

O	Original application site (first induction application).
M	Adjacent site for application after first strong reaction during induction.
M-1	Second adjacent site for application after second strong reaction during induction.
A	Naive adjacent site used during challenge application.
NP	Number of subjects not included in score totals: (see * below).
MU	Make-up session for subjects with earlier absence(s).

Symbols used to document deviation from experimental plan:

R	Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions.
X	Patch omitted due to previous strong test reaction(s).
XR	Patch omitted for reasons unrelated to the test.
L	Test patch worn less than 23 hours.
-	Subject absent.
*	Residual reaction to earlier application after absence. (Not included in score totals.)
N9G	No ninth grade.

INFORMED CONSENT STATEMENT

INTRODUCTION: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made as to the results of the study.

PURPOSE OF STUDY: This study involves research to see if the test articles (samples) can be put on human skin for long periods of time without causing irritation or allergies. Approximately 20 people will be involved in the study. The duration of the study is scheduled for six weeks but this could be extended if irritation or allergies are observed. Each participant will test one test article and a vehicle control. The test article is classified as a lubricant oil product.

STUDY PROCEDURES: The test articles will be placed on patches (small adhesive squares with a cotton pad). The patches will be put on the upper arm. Each patch will stay on your skin for 24 hours. Fresh patches will be applied nine times during the first three weeks followed by a 10-14 day rest period. On Monday of the sixth week, a double set of patches will be applied. You will come to the test location 13 times in six weeks.

FEMALES OF CHILDBEARING POTENTIAL: **You may not participate in this study if you are pregnant or nursing or trying to get pregnant. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study, and at the beginning of Week 4 and 6. You must also agree to use an adequate means of birth control.**

RISKS: Since the test is being done to see how the test articles affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin. On some occasions the reactions may spread beyond the patch.

Project No.: 94-1399-70

RISKS: (Continued)

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test articles or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy.

BENEFITS: The participants in this study will not benefit from the application of the test articles. But the results may all allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES: Because this is a safety study, alternative procedures are not applicable.

CONFIDENTIALITY: Hill Top Research will keep confidential, information concerning you that is obtained in connection with this study, except the Company whose product is being tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If, in the course of this study you experience illness, discomfort or injury, which appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research has elected to secure workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case emergency, contact Bonnie (Senior Project Leader) at 831-3114, ext. 2311 during business hours (M-F, 8 A.M.- 5 P.M.) or 249-2033 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114 or 1-800-669-1947.

Project No.: 94-1399-70

INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out on my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I've completed as outlined in the attached payment schedule. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am twenty-one years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this consent statement.

SUBJECT FULL
NAME PRINTED _____
ADDRESS _____

CITY _____ STATE _____ ZIP _____

TELEPHONE NUMBER _____ SOCIAL SECURITY NUMBER _____

SUBJECT
SIGNATURE _____ DATE _____

WITNESSED BY _____ DATE _____

SUBJECT NUMBER _____

Ref.: \patch\projects\941399.con

Institution: Hill Top Research, Inc.
Investigator: Robert A. Harper, Ph.D.
Study Title: Human Repeated Insult Patch Test (Full Panel)

Project No.: 94-1399-70
Page No.: _____

INFORMED CONSENT STATEMENT
REVISION #1

INTRODUCTION: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made as to the results of the study.

PURPOSE OF STUDY: This study involves research to see if the test articles (samples) can be put on human skin for long periods of time without causing irritation or allergies. Approximately 90 people will be involved in the study. The duration of the study is scheduled for six weeks but this could be extended if irritation or allergies are observed. Each participant will test one test article and a vehicle control. The test article is classified as a lubricant oil product.

STUDY PROCEDURES: The test articles will be placed on patches (small adhesive squares with a cotton pad). The patches will be put on the upper arm. Each patch will stay on your skin for 24 hours. Fresh patches will be applied nine times during the first three weeks followed by a 10-14 day rest period. On Monday of the sixth week, a double set of patches will be applied. You will come to the test location 13 times in six weeks.

FEMALES OF CHILDBEARING POTENTIAL: **You may not participate in this study if you are pregnant or nursing or trying to get pregnant. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study, and at the beginning of Week 4 and 6. You must also agree to use an adequate means of birth control.**

RISKS: Since the test is being done to see how the test articles affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin. On some occasions the reactions may spread beyond the patch.

Project No.: 94-1399-70

AJ#

RISKS: (Continued)

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test articles or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy.

BENEFITS: The participants in this study will not benefit from the application of the test articles. But the results may all allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES: Because this is a safety study, alternative procedures are not applicable.

CONFIDENTIALITY: Hill Top Research will keep confidential, information concerning you that is obtained in connection with this study, except the Company whose product is being tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If, in the course of this study you experience illness, discomfort or injury, which appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research has elected to secure workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case emergency, contact Bonnie (Senior Project Leader) at 831-3114, ext. 2311 during business hours (M-F, 8 A.M.- 5 P.M.) or 249-2033 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114 or 1-800-669-1947.

Project No.: 94-1399-70

Pg #

INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out on my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I've completed as outlined in the attached payment schedule. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am twenty-one years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this consent statement.

SUBJECT FULL
NAME PRINTED _____
ADDRESS _____

CITY _____ STATE _____ ZIP _____

TELEPHONE NUMBER _____ SOCIAL SECURITY NUMBER _____

SUBJECT
SIGNATURE _____ DATE _____

WITNESSED BY _____ DATE _____

SUBJECT NUMBER _____

Ref.: \patch\projects\941399.con

Institution: Hill Top Research, Inc.
Investigator: Robert A. Harper, Ph.D.
Study Title: Human Repeated Insult Patch Test (Full Panel)

Project No.: 94-1399-70
Page No.: _____

INFORMED CONSENT STATEMENT
REVISION #1

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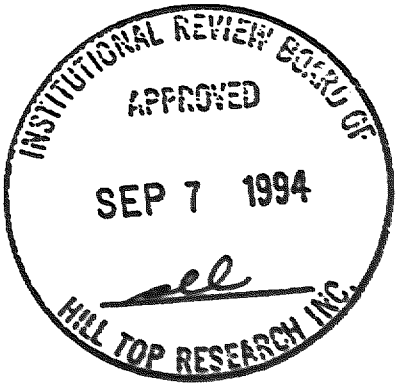
PURPOSE OF STUDY: This study involves research to see if the test articles (samples) can be put on human skin for long periods of time without causing irritation or allergies. Approximately 90 people will be involved in the study. The duration of the study is scheduled for six weeks but this could be extended if irritation or allergies are observed. Each participant will test one test article and a vehicle control. The test article is classified as a lubricant oil product.

STUDY PROCEDURES: The test articles will be placed on patches (small adhesive squares with a cotton pad). The patches will be put on the upper arm. Each patch will stay on your skin for 24 hours. Fresh patches will be applied nine times during the first three weeks followed by a 10-14 day rest period. On Monday of the sixth week, a double set of patches will be applied. You will come to the test location 13 times in six weeks.

FEMALES OF CHILDBEARING POTENTIAL: **You may not participate in this study if you are pregnant or nursing or trying to get pregnant. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study, and at the beginning of Week 4 and 6. You must also agree to use an adequate means of birth control.**

RISKS: Since the test is being done to see how the test articles affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin. On some occasions the reactions may spread beyond the patch.



RISKS: (Continued)

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test articles or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy.

BENEFITS: The participants in this study will not benefit from the application of the test articles. But the results may all allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES: Because this is a safety study, alternative procedures are not applicable.

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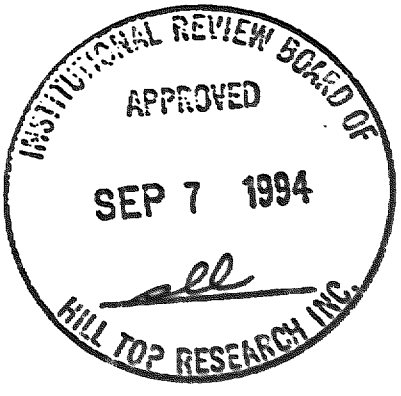


Project No.: 94-1399-70

INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out on my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I've completed as outlined in the attached payment schedule. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am twenty-one years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this consent statement.

SUBJECT FULL
NAME PRINTED _____
ADDRESS _____

CITY _____ STATE _____ ZIP _____

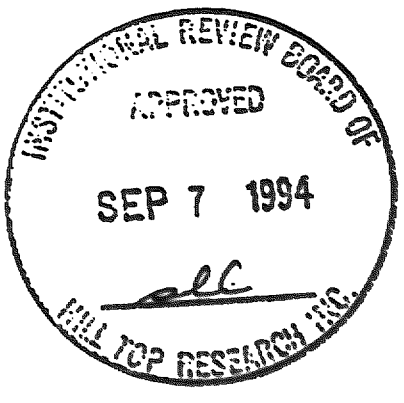
TELEPHONE NUMBER _____ SOCIAL SECURITY NUMBER _____

SUBJECT
SIGNATURE _____ DATE _____

WITNESSED BY _____ DATE _____

SUBJECT NUMBER _____

Ref.: \patch\projects\941399.con



Ref. No.: 94-1399-70

October 21, 1994

PROTOCOL AMENDMENT NO. 2.

The following changes apply to the protocol:

1) Test Article B will be applied under semi-occluded conditions to the 90 additional subjects empaneled. The patch condition was listed incorrectly in Protocol Amendment No. 1.

2) The Primary Coordinator of the study will be Martha E. Plaza, Test Operations Supervisor, rather than Grace E. Kenney, Test Area Supervisor.

Submitted by: Martha E. Plaza 10/24/94
Martha E. Plaza, M.B.A. Date
Test Operations Supervisor

Approved by: Robert A. Harper 10/24/94
Robert A. Harper, Ph.D. Date
Investigator

INSTITUTIONAL REVIEW BOARD OF HILL TOP RESEARCH, INC.
APPROVED
OCT 25 1994

for Carl A. Blunde, M.D., Ph.D.
Robert McMaster, M.D. Date
Institutional Review Board Chairman

HILL TOP RESEARCH, INC.
P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/831-1217

Ref. No.: 94-1399-70

December 6, 1994

PROTOCOL AMENDMENT NO. 3

Subject No. 31 will participate in a confirmatory rechallenge. The subject will be patched to Test Article B on original (right arm) and naive (lower back) sites. The patches will be worn for 24 hours and removed by the subject. Scoring of the sites will be at 48 and 96 hours after application.

Submitted by: Martha E. Plaza 12/7/94

Martha E. Plaza, M.B.A. Date
Test Operations Supervisor

Approved by: Robert A. Harper 12/6/94

Robert A. Harper, Ph.D. Date
Investigator

Robert H. McMaster, M.D. 12/8/94

Robert McMaster, M.D. Date
Institutional Review Board Chairman

INSTITUTIONAL REVIEW BOARD OF
APPROVED
DEC 8 1994
HILL TOP RESEARCH INC.

HILL TOP RESEARCH, INC.
P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/831-1217

Institution:	Hill Top Research, Inc.	Proj. No.: 94-1399-70
Investigator:	Robert A. Harper	Page No.:
Study Title:	Confirmatory Rechallenge	

INFORMED CONSENT STATEMENT

INTRODUCTION: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the study procedures. This study is designed to see if test articles can be put on human skin without causing irritation or allergies.

PURPOSE OF STUDY: You recently took part in a patch test for Hill Top Research, Inc. This study involves follow-up research to see if the test articles caused irritation or allergies. The duration of the study is scheduled for one week but this could be extended an additional one or two weeks if reactions are experienced. You will test two test articles classified as lubricant oil products.

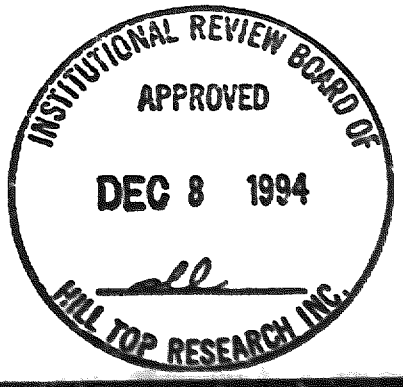
STUDY PROCEDURES: The test articles will be put on your right arm and lower back with patches (small adhesive squares with cotton pads). The test articles are on the pads. Each pad will stay on your skin for 24 hours. You will remove the patches at home. The skin sites will be evaluated on Day 2 and 3. You will come to the test location three times in five days.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent, you must agree to have a urine pregnancy test at the start of the study and at the end of the study. You must also agree to use an adequate means of birth control.

RISKS: Since the test is being done to see how the samples affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin.

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test products or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy. However, the chance of an allergy is considered unlikely.



BENEFITS: The participants in this study will not benefit from the application of test materials but the test results may allow a new product to be marketed.

ALTERNATIVE PROCEDURES: Because this is a safety study, alternative procedures are not applicable.

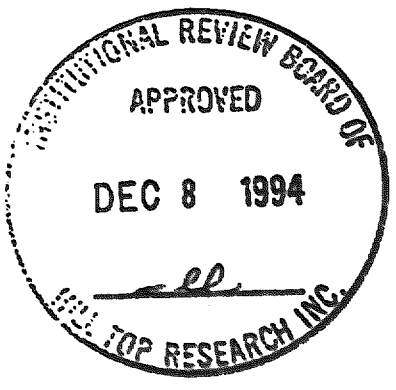
CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, Inc., except that the Company whose product is being tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be the result of the study, Hill Top Research, Inc. will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the Investigator or Study Manager who will discuss it with you to determine if it has been caused by your participation in the study.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research, Inc. has elected to secure workers' compensation coverage for participants in its studies and tests and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case of emergency, contact Bonnie (Project Leader at 831-3114, ext. 2810 during business hours (M-F, 8am - 5pm) or 249-2036 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114.

VOLUNTARY PARTICIPATION: Your decision to participate in this research study is strictly voluntary. Your refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled.



Proj. No.: 94-1399-70

INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out of my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I have completed as outlined in the attached payment schedule. If, in the judgement of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

If I am a female of childbearing potential, I am not now pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am 18 years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this informed consent.

SUBJECT FULL NAME PRINTED _____

ADDRESS _____

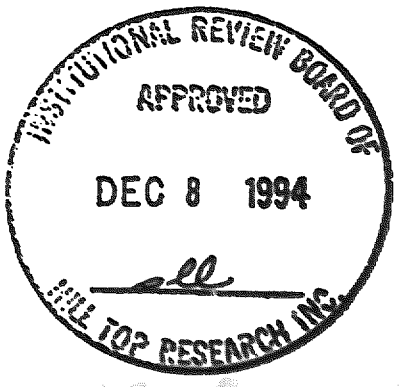
CITY _____

TELEPHONE NUMBER _____ _____ SOCIAL SECURITY NUMBER _____

SUBJECT SIGNATURE _____ DATE _____

WITNESSED BY _____ DATE _____

SUBJECT NUMBER _____



HILL TOP RESEARCH, INC.

IMPORTANT NOTICE

Hill Top Research, Inc. submits this report with the understanding that no portion of it will be used for advertising or promotion without obtaining our prior written consent to the specific proposed use. When such use is desired we will be glad to assist in the preparation of mutually acceptable excerpts or summaries.

TEST ARTICLE PROCEDURE

Unless the Sponsor requests otherwise, it is Hill Top Research's practice to store test articles for one (1) month after a study is concluded. The test articles are then destroyed.

New drugs and investigational devices are handled on an individual basis as worked out with the Sponsor.

DATA RETENTION

All study documents and the original final report will be on file in the Hill Top Companies archives for a period of not less than two years, unless indicated otherwise on the Study Summary and Authorization Form. A permanent record will be retained in the form of microfilm.

Proj. E:.	94-1399-70
Page No.	

Ref.: 94-1399-70

August 9, 1994

Protocol Amendment No. 1

At least 90 additional subjects will be empaneled to evaluate the potential for Test Article B to elicit contact sensitization under occluded conditions. These additional subjects will complete a full 100 plus panel for this test article. Subjects will also receive Test Article A (mineral oil).

Submitted by: Grace E. Kenney 8/19/94

Grace E. Kenney, M.S. Date
Test Area Supervisor

Approved by: Robert A. Harper 8/26/94

Robert A. Harper, Ph.D. Date
Investigator

Robert H. McMaster, M.D. 9/7/94

Robert McMaster, M.D. Date
IRB Chairman

INSTITUTIONAL REVIEW BOARD OF
APPROVED
SEP 7 1994
HILL TOP RESEARCH INC.

HILL TOP RESEARCH, INC.
P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/831-1217
The Hill Top Companies
Hill Top Research, Inc. • Hill Top Pharmatest, Inc. • Hill Top Biolabs, Inc.